UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	**MDL No. 1456**
	)	**Master File No. 1:01-CV-12257-PBS**
	)	**Sub-Category Case No. 1:08-CV-11200**
THIS DOCUMENT RELATES TO ***United States ex rel. Linnette Sun and Greg Hamilton, Relators v. Baxter Hemoglobin Therapeutics and Baxter International, Inc.***	)	**Judge Patti B. Saris**

MEMORANDUM IN OPPOSITION TO BAXTER INTERNATIONAL INC.'S MOTION TO DISMISS RELATORS' COMPLAINT

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BACKGROUND

In May of 2000 First DataBank entered into an agreement with the National Association of Medicaid Fraud Control Units to stop reporting average wholesale prices (AWPs) published by the manufacturers and to begin reporting actual market prices (and ultimately Wholesale Acquisition Cost) for a number of drug and biologic products, including a number of Baxter's biologic products. This set the stage for an entirely new species of AWP fraud. Instead of falsely reporting AWPs, Baxter, knowing that First DataBank was hamstrung, refused to report its WAC for Recombinate, and instead sent FDB a letter claiming a "list price" of $1.31 – knowing that FDB would multiply this by 125% , resulting in a reported AWP of $1.64.

Relator Linnette Sun, a Baxter pricing director, and Greg Hamilton, a business associate of Baxter's management each discovered pieces of this new scheme.

Because the scheme could not even have existed before the reporting mechanism changed in 2000, prior complaints and articles discussing other forms of AWP fraud disclose nothing at all and are irrelevant. Moreover, one of the largest selling biological products listed in the complaint, Advate, was not even approved by the FDA until July 28, 2003 and likewise could not have been the subject of earlier disclosures.

In early 2005, relators' counsel, discussed these allegations with an AUSA well-versed in AWP litigation who responded that he was quite interested in it, and agreed to read a draft complaint. sent him a draft complaint. The AUSA told me that he looked forward to working on the case.

SUMMARY OF ARGUMENT

The Court has jurisdiction over these claims because this is an entirely new species of fraud which could not and did not exist until late 2000, and one of the key drugs involved was not even approved until 2003. The relators were each well positioned to gain, and *did* gain direct and independent knowledge of the schemes, and shared them with the Government in January of 2005, nearly three months before they filed the case on April 22, 2005. Thus, even if the Court finds that there was a public disclosure of the allegations in relators' complaints, relators remain the original sources.

Finally, the complaint is sufficiently specific to meet the 9b requirements.

ARGUMENT

1. RELATORS' ALLEGATIONS CONCERNED AN ENTIRELY NEW SPECIES OF AWP FRAUD WHICH HAD NOT BEEN PUBLICLY DISCLOSED PRIOR TO THEIR COMPLAINT.

Relators' allegations are based on Baxter's intentionally forcing First DataBank ("FDB") to misreport Baxter's prices for biological products by refusing to give FDB any WAC information. This scheme was based on FDB's 2000 consent decree with the Department of Justice, and consequently could not have been publicly disclosed in any of the earlier filed complaints cited by Baxter. Moreover, Relators' complaint includes allegations about Advate, a drug which did not even come on to the market until July 28, 2003, long after the "disclosures" Baxter claims to have found.

Baxter argues that this Court lacks jurisdiction because Relators' AWP, Best Price, and Volume Committed Contract allegations were publicly disclosed in litigation before Relators'

filed their Complaint.[1] But Baxter's assertion is not supported by any substantive comparisons to Relators' Complaint. Instead, Baxter chiefly relies on generic references to the Master Consolidated Class Action Complaint ("MCC") and the State of Nevada's Complaint.[2]

A. Allegations that Baxter Refused to Give WAC Information to First DataBank, Knowing that First DataBank Would Apply a Multiplier to Baxter's Claimed List Price, Were Altogether New.

(1) Prior Complaints

First, although Baxter claims that Relators' AWP allegations were publicly disclosed in "[n]o fewer than 38 AWP complaints," it manages to cite only a single phrase in the MCC. "In the MCC, Plaintiffs specifically alleged that Baxter 'engaged in an ongoing deliberate scheme to inflate AWPs in order to increase the market share of its products.'"[3] Other than this single sentence—and one general paragraph reference to the State of Nevada's complaint—Baxter concludes, without foundation, that all the other complaints make similar allegations.[4] Despite reference to "38 AWP complaints" Baxter fails to cite any references to specific drugs, prices, contracts, AWP calculations, or any other substantive issue included in Relators' Complaint. As stated in Relators' Complaint, "[p]rior to May of 2000 FDB's misreporting of price information was suspected or known by state Medicaid agencies. However, in May of 2000 FDB entered into an agreement with the Department of Justice and various states to stop reporting AWPs

[1] Defendants' Motion, pp. 5-6.

[2] Defendants' Motion, p. 5.

[3] Defendants' Motion, p. 5 (citing MCC ¶ 212).

[4] Defendants' Motion, p. 5 ("All of the other prior complaints make similar allegations regarding AWP and/or WAC inflation.").

published by the manufacturers and to instead report them on the basis of market prices. FDB subsequently based its reports on surveys of wholesalers."[5]

Unlike the complaints generically cited by Baxter, Relators' Complaint is based on Baxter intentionally misstating its market prices–knowing that FDB would be required, under the consent decree, to repeat these misstatements to governmental entities. "Baxter falsely reported WAC by claiming it was reporting a 'list sales price.'"[6] "Medicaid, Medicare, and all other systems which base reimbursement rates for drugs on the published AWP rely upon the accuracy of the AWP, and, in turn, depend upon the honesty and accuracy of Baxter and other drug manufacturers in reporting WAC to FDB."[7] Baxter fails to point out one single reference to this type of fraud in any of the complaints that it cursorily cites.

(2) Prior Government Reports

Four of the Government reports listed originated long before the change in price reporting was required by DOJ and the NAMFCU. One of them (Defendant's Exhibit J) describes some of the changes in the reporting structure which enabled Baxter to commit the fraud, but falls far short of even mentioning the scheme itself. Defendant's Exhibits K discusses Baxter's pricing in the mid-1990s (Exhibit K, Attachment 7, pp. 33-36), long before this fraudulent scheme was possible. Lastly, Exhibit L makes absolutely no mention of Baxter's manipulation of the new strictures on price reporting. The government reports cited by Baxter simply confirm Relators'

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[5] Relators' Complaint ¶ 24.

[6] Relators' Complaint ¶ 38.

[7] Relators' Complaint ¶ 25.

point – no one in government had an inkling about this new fraud scheme until Relators brought it to the Government's attention.

(3) News Media Reports

First, none of the reports cited ever mention anything remotely like resembling Baxter's scheme. Second, the April 2000 Marketing Research Bureau report and the 1996 *Barron's* article (Deft.'s Brief, p. 8) the both predate even the possible existence of the FDB-based scheme.

Finally, the Marketing Research Bureau Report is not even a report from the "news media". This report costs $16,000 per year and has an industry-based circulation of only approximately twenty copies, none of which go to public or university libraries.[8] The subscribers are manufacturers, a few specialty pharmacies, and a few 340d entities (e.g. Baxter, Bayer Corp., Wyeth Pharmaceuticals . . . .).[9]

To be considered a public disclosure, the Court must first examine whether the MRB is in fact disseminated to the public. "[I]t is generally accepted that publicly available documents, such as a complaint filed in conjunction with a civil lawsuit, qualify as public disclosures under the statute."[10] Unlike filed complaints or a newspaper article, the MRB is not available to "any stranger to the fraud."[11] At $16,000 per copy, industry insiders such as Baxter are the only

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[8] Hamilton Decla., ¶ 14.

[9] Hamilton ¶ 14.

[10] In re Pharmaceutical Industry AWP Litigation, 538 F. Supp. 2d 367, 376-77 (D. Mass. 2008).

[11] See United States ex rel. Pentagen Technologies Int'l, Ltd. v. CACI Int'l Inc., No. 94 Civ. 2925, 1996 WL 11299, *8 (S.D.N.Y. Jan.4, 1996)

subscribers that can afford such a prohibitive cost. For similar reasons, courts held that foreign news articles are not public disclosures because they are not accessible to the American public.[12] Although many Americans speak foreign languages, few would be capable of spending $16,000 to access the MRB.

B. Allegations that Baxter Concealed the Discounts Given With Volume Committed Contracts and Thereby Concealed the Best Price from CMS and Underpaid Rebates to the States Were Not Publicly Disclosed.

Baxter next argues that Relators' Best Price allegations, contained at ¶¶ 49-5, ¶¶ 53 - 60 of the Complaint, were publicly disclosed.[13] Yet again, Baxter fails to specifically point out what was publicly disclosed. Rather, it makes generic allusions to the Nevada Complaint, the Montana Complaint, and the County of Nassau Complaint.[14] Although Baxter claims that Relators' allegations involving "Volume Committed Contracts" were publicly disclosed in the

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[12] See, e.g., United States ex rel. Yannacoupolous v. General Dynamic, 315 F. Supp. 2d 939, 949 (N.D. Ill. 2004) ("There is no public disclosure to the American public when information is divulged in a foreign publication, especially if published in a foreign language. In this case, publication in Greek-language news media did not publicly disclose information to the American public.").

[13] Defendants' Motion, p. 5 ("The Best Price allegations in Relators' Complaint ¶ ¶ 49-51, 53-61, 85-88 (Count III), also were asserted in earlier lawsuits against Baxter.").

Defendant also argues that it was improper to plead Stark violations because it could not be liable under the terms of the Stark Act. (Defendants' Motion, p. 22). This argument is correct. However, it does not relieve Baxter of liability for concealing the discounts from CMS, and thereby underpaying rebates to the states. Relators below discuss their request for leave to amend their complaint to plead that the same facts establish violations of the Anti Kickback Statute, §42 U.S.C. 1320a-7b(b) as well as cognate state statues, e.g., California Welfare & Institutions Code §14107.2

[14] Defendants' Motion, p. 5 ("The Nevada Complaint, for example, charged Baxter with misrepresenting its Best Prices. Exhibit B ¶¶ 137-152. So, too, did other state Attorney General and New York County lawsuits.") (citing Exhibits C and D).

MCC and Nassau County Complaint, those complaints never identify the drugs involved..[15] The complaint, in contrast identifies two specific drugs. "In an April, 2003 meeting to discuss pricing policy for Advate and Recombinate, Bradley declared that the U.S. marketing team was not worried about losing market share to competitors because they had Volume Committed Contracts for most of their products which would be in force for the next three years."[16] Relator discussed a specific contract, the meeting when it was discussed, and which employees were present. "The contract was read by Relator, Poulios, and John Park (Defendant's Global Products Director)."[17] In contrast, the Nassau County Complaint fails to give factual detail about any Volume Committed Contract. Rather, it only vaguely refers—in a single sentence—to volume discounts. "Manufacturers or wholesalers also offer purchasers rebates based on the volume of products purchased not in a single sale but over a period of time."[18]

C. Even if Prior Suits or Government or News Media Reports Are Considered Public Disclosures, the Relators Are Original Sources.

Last year this Court made clear its analysis of the original source exception to the public disclosure bar. *In re Pharmaceutical Industry AWP Litigation*, 538 F. Supp. 2d 376, supra. The Court grounded its analysis in recognition that Congress was "[s]eeking the golden mean

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[15] Defendants' Motion, pp. 5-6 ("Moreover, a number of the complaints refer to alleged improprieties concerning volume discounts, similar to the Best Price allegations related to 'Volume Committed Contracts' in Relators' Complaint ¶ 51. See, e.g., MCC ¶ 165 (referring to 'volume discounts, rebates, off-invoice pricing, free goods,' etc.); (Nassau County Complaint) ¶¶ 95, 96 (discussing alleged improprieties associate with volume discounts, wholesaler chargebacks, and volume-based rebates).").

[16] Relators' Complaint ¶ 50.

[17] Relators' Complaint ¶ 50.

[18] Defendants' Motion, Exhibit D ¶ 96.

between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own." Direct knowledge is "firsthand knowledge of the alleged fraud" obtained through the relator's "own labor unmediated by anything else." *Id.*, at 384. Independent knowledge is knowledge independent of the public disclosure. *Id.* At 380.

Thus in *In re Pharmaceutical Industry AWP Litigation [U.S. ex rel West, et. al. v. Ortho-McNeil Pharmaceutical and Johnson & Johnson*) the Court first determined whether a public disclosure had occurred, and, if it had, then analyzed whether or not the relator's knowledge of the fraud was direct and independent. Applying this reasoning, the Court found that verbal statements from the relator's manager were sufficient to establish direct and independent knowledge. *Id.,* at 386 (being told to bribe a hospital with a cash payment). Notwithstanding the fact that "earlier lawsuits alleged a long-term industry-wide practice of providing various financial incentives", those industry-wide practices were not "adequate to set the government squarely on the trail of fraud" as compared with the Relator's allegations of "a very specific fraudulent scheme". *Id.*, at 387.

In essence, if the Relators here are able only to describe a previously disclosed pattern and practice, they are not original sources. If they have specific knowledge they derived on their own that can "set the government squarely on the trail" of specific schemes, they are original sources, even though the general class of scheme may have been previously disclosed. And so long as that knowledge is independent, it can be derived from the statements of others, such as managers. *Id.*, at 386.

1. Relators Have Direct and Independent Knowledge of Relevant Information.

Applying these standards, each Relator independently interacted with an overlapping set of Baxter pricing decision makers. Each Relator learned of Baxter's schemes from such communications.

A. Linnette Sun Has Direct and Independent Knowledge of Any Arguably Disclosed Allegations

In 2002 Linnette Sun, an economist, was hired as Director of Medical Outcomes Research and Economics. Her primary responsibility was pricing a billion dollar biological product, Advate.[19] Even before her official start date, Sun participated in a meeting to secretly discuss and decide upon the WAC and list price that Baxter would report to First DataBank.[20] She heard the other pricing and sales executives state that the spread between AWP and actual price to home health companies still had be manipulated in order to maintain or increase Baxter's market share.[21] Sun was also told by senior managers that even if patients were given drug overdoses by home health companies seeking to fulfill their volume commitments, that the overdoses could be achieved without "serious" side effects.[22]

In mid 2003 Sun attended a meeting where Larry Guiheen, President of Baxter BioScience and other managers worked out a plan to artificially "set" the Average Wholesale

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[19] Sun Decla., ¶5. Notwithstanding her title, she ahd not responsibility for medical outcomes research.

[20] Sun Decla., ¶¶6-7.

[21] Sun Decla, ¶¶ 8-10, 16

[22] Sun Decla, ¶12.

Price, but to disguise it in reports as the "list price". Guiheen ordered Sun and the other participants to destroy all copies of an incriminating spreadsheet what was used by participants during the meeting.[23]

When Sun discovered Baxter's misuse of "list price" reporting to First DataBank she notified her supervisors, but was ordered by Guiheen to drop her research into this scheme.[24]

Linnette Sun has direct and independent knowledge of the deliberate misreporting to First DataBank, the use of these reports to manipulate the spread, and of Baxter's knowledge that it had to conceal from the government the discounts given to home health agencies.

B. Greg Hamilton Has Direct and Independent Knowledge of Any Arguably Disclosed Allegations

Baxter is being somewhat disingenuous in its brief when it claims that Hamilton "was never employed by, nor had any association with Baxter." [25] In fact, Hamilton had numerous meetings with Larry Guiheen and Guiheen's supervisor, Peter O'Malley. These meetings focused on Baxter's pricing structure for the very biologicals at issue in this Complaint.[26] Hamilton was invited to hold these discussions with Baxter because of his expertise in the specialty pharmacy market and his knowledge of biologic products for hemophilia.[27]

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[23] Sun, Decla ¶14.

[24] Sun Decla, ¶15.

[25] Defendant's Brief, p. 11.

[26] Hamilton Decla., ¶ 2.

[27] Hamilton Decla., ¶ 3.

Some of these discussions specifically concerned Baxter's pricing of Advate.[28]

Hamilton likewise learned of Baxter's "list price" scheme to manipulate First DataBank when an FDB manager called him up and asked his advice about this scheme.[29] Baxter protests that this knowledge is somehow not "direct". The fact remains that Hamilton learned enough about a specific fraudulent scheme to set the Government squarely on the trail of the fraud.

Greg Hamilton has direct and independent knowledge of the deliberate misreporting to First DataBank as a means of maintaining or enhancing the spread. He also has direct and independent knowledge of Baxter's efforts to manipulate AWP for the benefit of home health companies.

2. Relators Furnished Information About Their Allegations to the Federal Government Well Before Filing Their Lawsuit

Nearly three months before filing, Relators, through their counsel, informed Assistant United States Attorney Michael Theis of the Relators' allegations. Before taking his position as an AUSA in Colorado, Mr. Theis had been a Trial Attorney at the Department of Justice, where he had been primarily responsible for developing DOJ's liability theories for AWP cases. During a forty-minute conversation Kleiman apprised Theis of Baxter's effort to continue to manipulate AWP by refusing to report to FDB what its wholesale acquisition cost was, and Baxter's concealment of volume-based discounts. Kleiman sent Theis a draft of the complaint and, after Theis had reviewed it, they had a second conversation before the suit was filed.[30]

Relators thus voluntarily disclosed their allegations to the Government well before the

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[28] Hamilton Decla., ¶ 6.

[29] Hamilton Decla., ¶¶ 8-10.

[30] Kleiman Decla., ¶¶ 1-3.

case was filed.

D. The Complaint Has Been Plead With Sufficient Particularity

Defendants argue that the Court should dismiss Relators' AWP and best price claims under FED. R. CIV. PROC. 9(b) ("Rule 9(b)"), chiefly relying on the First Circuit's recent opinion in Duxbury to support this argument.[31] But Defendants failed to mention that the Duxbury parties entered a joint dismissal of the AWP and best price allegations (contained in Count II) more than two years before the opinion was issued.[32] Thus, those allegations were not before the First Circuit.

Discussing the district court's dismissal of these counts, the First Circuit stated that "[h]aving established its subject matter jurisdiction, the court nevertheless dismissed the 1992 through 1998 kickback claims [Count I] because the Amended Complaint failed to plead the claims with sufficient particularity under Rule 9(b). . . . As to Count III, the court dismissed the claims concerning 'off-label' promoting because they were barred by the 'first-to-file' rule." After the First Circuit reversed the district court and held that Duxbury's kickback claims were sufficient under Rule 9(b), it limited its discussion of Rule 9(b) to the specific facts (i.e. kickbacks) in the case, stating that '"[w]e decline to draft a litigation manual full of scenarios" of what allegations would be sufficient for purposes of Rule 9(b). Suffice it to say that we limit our

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[31] Memorandum in Support of Baxter International Inc.'s Motion to Dismiss Relators' Complaint, ("Defendants' Motion") p. 17 ("Relators' allegations concerning the Pricing Schemes are grossly insufficient under Rule 9(b), and therefore Counts I and III must be dismissed."), citing Duxbury v. Ortho Biotech Products, L.P., No. 08-1409, 2009 WL2450716 (1st Cir. Aug. 12, 2009).

[32] Duxbury, 2009 WL 2450716 *19, n.5 ("Count II of the Amended Complaint alleges that OBP engaged in a scheme to publish a fraudulently inflated AWP for Procrit. On June 27, 2007, the parties jointly stipulated to the dismissal of this count.").

holding to the facts.'"[33] Duxbury is simply inapplicable to the AWP manipulation alleged in Relators' Complaint.

This Court has explained that Rule 9(b) does not require Relators to plead evidence. "The requirements of Rule 9(b), however, must be read in conjunction with Fed.R.Civ.P. 8(a), which requests "a short and plain statement of the claim" for relief. Thus, while Relator must allege the circumstances of the fraud, he is not required to plead all of the evidence or facts supporting it."[34] "[I]n determining the adequacy of a complaint under that rule [Rule 9(b)], we cannot hold plaintiffs to a standard that would effectively require them, pre-discovery, to plead evidence."[35]

In Iqbal, the Supreme Court held that a complaint need only show that unlawful conduct was facially plausible.[36] The Court held that a "pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action' is insufficient."[37] "In reviewing the complaint in Iqbal, the Court noted that the complaint did not contain any factual allegations

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[33] Duxbury, 2009 WL 2450716 *17 (citations omitted) (quoting United States ex rel. LeBlanc v. Raytheon Co., 913 F.3d 17, 20 (1st Cir.1990)).

[34] *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46-47 (D. Mass. 2001).

[35] *Shaw v. Digital Equipment Corp.*, 82 F.3d 1194, 1225 (1st Cir. 1996), *superseded by* Private Securities Litigation Reform Act, 15 U.S.C. § 78u-4(b)(1)-(2).

[36] Ashcroft et al. v. Iqbal et al., 129 S.Ct. 1937, 1940 (2009) ("A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.").

[37] Id. at 1949.

claiming that Mueller or Ashcroft may have intentionally discriminated on the basis of race or religion."[38]

Here, unlike Iqbal's allegations, or even under the limited holding of Duxbury, Relators' Complaint is sufficient under Rule 9(b) because Relators do more than just "'suggest fraud was possible.'"[39] In reversing the district court, the First Circuit refused to require that relators plead specific instances of fraud to pass Rule 9(b). "In applying Rule 9(b), the district court held that the rule 'requires relators to 'provide details that ***identify particular false claims*** for payment that were submitted to the government.' This was error."[40] Under Duxbury, an FCA complaint is sufficient to pass Rule 9(b) without providing specific details of each false claim, especially where, as here, the claims are actually submitted by third parties, and not by the defendant.[41] And this more flexible standard[42] has been applied in two other recent circuit opinions.[43]

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[38] Al-Kidd v. Ashcroft, __ F.3d __, 2009 WL 2836448 *21 (9th Cir. Sept. 4, 2009).

[39] Duxbury, 2009 WL 2450716 *15 (stating that "unlike in Rost, Duxbury does more than 'suggest fraud was possible.'").

[40] Duxbury, 2009 WL 2450716 *14 (emphasis in original).

[41] Duxbury, 2009 WL 2450716 *14 ("[W]e held that a relator could satisfy Rule 9(b) by providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility' without necessarily providing details as to each false claim.") (quoting United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 733 (1st Cir.2007)).

[42] Duxbury, 2009 WL 2450716 *15 (holding that Duxbury's claims satisfy Rule 9(b) under this 'more flexible standard'") (quoting United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 46 (1st Cir.2009)).

[43] See e.g., United States ex rel. Lusby v. Rolls-Royce Corp., 570 F.3d 849, 854 (7th Cir. June 30, 2009) ("We don't think it essential for a relator to produce the invoices (and accompanying representations) at the outset of the suit. True, it is essential to show a false statement. But much knowledge is inferential-people are convicted beyond a reasonable doubt of conspiracy without a written contract to commit a future crime-and the inference that Lusby proposes is a plausible one. . . . To say that fraud has been pleaded with particularity is not to say

Relators' Complaint alleges factual details to infer that Baxter's illegal pricing schemes were more than merely possible.

In this case, Relators' Complaint alleges details and factual support of Baxter's fraudulent pricing schemes. The Complaint describes the market for drug products and lists specific drugs and biologics that Baxter manufactures. Complaint, ¶ 20. It describes, in detail, how Baxter's drugs and biologics are covered by Government programs. Complaint, ¶ 21. It covers how Baxter is supposed to calculate its pricing and chronicles Baxter's history of misreporting prices to First Data Bank ("FDB"). Complaint, ¶ ¶ 22-26. It alleges exactly how Baxter cherry picked its highest prices and then falsely reported them to FDB as its lowest prices. Complaint, ¶ ¶ 27-35. It details how Baxter misreported the price of Recombinate (Complaint, ¶ ¶ 36-42) and Advate, including how Baxter sold Advate for $0.99 per dose, but reported its "lowest price" as $1.60. Complaint, ¶ ¶ 43-46. Further, it discusses a specific contract that was illegal. Complaint, ¶ 51.[44] Finally, it identifies specific employees, including Sun's supervisors, that were put on notice about these illegal practices.

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that it has been proved (nor is proof part of the pleading requirement)".); United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. April 8, 2009) ("[A] relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted").

[44] Although Baxter refers to this contract in its motion, it fails to explain how such specific pleading places the Complaint outside the bounds of Rule 9(b). Defendants' Motion, p. 14.

Out of an abundance of caution, Relators ask that if the Court finds that the Complaint is insufficient under Rule 9(b), that they be given leave to amend.[45]

2. **RELATORS' STATE LAW CLAIMS SURVIVE FOR THE SAME REASON THAT THEIR FEDERAL CLAIMS SURVIVE**

Defendants argue that this Court should dismiss Relators' state law claims for various reasons, which are addressed more specifically below. It should be noted at the outset, however, that Relators' state law claims survive for the same reasons that Relators' federal claims survive—namely that they are plead with sufficient particularity, they were not publicly disclosed, or the Relators are nonetheless original sources. As discussed, Relators' allegations are based on intentionally forcing First DataBank ("FDB") to breach its agreement with the Department of Justice and the National Association of Medicaid Fraud Control Units, representing the states. "Baxter falsely reported WAC by claiming it was reporting a 'list sales price.'"[46] "Medicaid, Medicare, and all other systems which base reimbursement rates for drugs on the published AWP rely upon the accuracy of the AWP, and, in turn, depend upon the honesty and accuracy of Baxter and other drug manufacturers in reporting WAC to FDB."[47] This scheme was not publicly disclosed in any of the sources cited by Baxter. Moreover, Relators' Complaint alleges details and factual support of Baxter's fraudulent pricing schemes.[48]

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[45] Fed. R. Civ. Proc. 15(a); *See, e.g.*, *Foman v. Davis*, 371 U.S. 178, 182 (1962) ("'Rule 15(a) declares that leave to amend 'shall be freely given when justice so requires'; this mandate is to be heeded.").

[46] Relators' Complaint ¶ 38.

[47] Relators' Complaint ¶ 25.

[48] Relators' Complaint, ¶ ¶ 20-51.

3. **RELATORS CONCEDE THAT THE STATE LAW CLAIMS REGARDING ARKANSAS AND UTAH SHOULD BE DISMISSED.**

Defendants are correct. The Court should dismiss Counts XX and XXI (the Arkansas and Utah claims) because there is no private right of action under those statutes.[49] Relators agree that these counts should be dismissed.[50]

4. **RELATORS AGREE THAT THE TEXAS AND NEVADA STATE CLAIMS SHOULD BE DISMISSED.**

Defendants are correct. The Court should dismiss Count XII of Relators' Complaint based on the June 2006 settlement with the State of Texas.[51] Relators have already executed a release as to Defendants' violations of the Texas False Claims Act and agree that this count should be dismissed.[52]

Defendants are also correct that the Court should dismiss Count XVI of Relators' Complaint based on the August 2008 settlement with the State of Nevada.[53] And, admittedly, the settlement includes a broad release related to commercial price reporting services, which arguably includes First Data Bank.

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[49] Defendants' Motion, p. 20, ¶ II(B).

[50] Relators note for the record that this was never the subject of any meet and confer communications from Baxter, and that Relators would have readily conceded this point (and saved the Court time) had it been pointed out to them.

[51] Defendants' Motion, p. 20, ¶ II(C)(5).

[52] Relators note for the record that neither the Texas nor the Nevada settlements were ever the subject of any meet and confer communications from Baxter, and that Relators would have readily conceded this point (and saved the Court time) had it been pointed out to them.

[53] Defendants' Motion, p. 20, ¶ II(C)(4).

Unlike the other settlement agreements cited by Defendants (California, Hawaii, and Illinois), this settlement agreement explicitly details similar conduct as discussed in Relators' Complaint. The agreement purports to release "claims regarding any drug price published by any commercial price reporting service, or provided by any Released Party to any such commercial price reporting service . . . ."[54] The Nevada Complaint was executed at least five (5) months before the other settlement agreements. Thus, had the parties intended that similar conduct be released in the California, Hawaii, and Illinois settlements, they would have included similar language. But they failed to do so. Relators agree that the Nevada count should be dismissed.

5. **THE CALIFORNIA, HAWAII, AND ILLINOIS CLAIMS SHOULD NOT BE DISMISSED BECAUSE RELATORS' ALLEGATIONS WERE NOT PART OF THE COVERED CONDUCT ENUMERATED BY THE SETTLEMENT AGREEMENTS.**

Defendants argue that the Court should dismiss Count VIII, IX, and X of the Complaint based on settlements with the States of California, Hawaii, and Illinois, entered into between December, 2008 and March, 2009[55] But Relators' allegations were not included in those settlements nor released by those states.

Defendants' settlement agreement with the State of California only applied to "covered conduct." And that "covered conduct" does not include Defendants' intentionally lying to FDB about its market prices—knowing that FDB would submit those prices to governmental entities.[56]

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[54] See Exhibit T, p. 5 ¶4, attached to Defendants' Motion.

[55] Defendants' Motion, p. 20, ¶ II(C).

[56] See Exhibit Q ¶ C, attached to Defendants' Motion.

All other conduct was specifically excluded from the terms of the settlement agreement. "[S]pecifically reserved and excluded from the scope and terms of this Agreement, and from the scope and terms of the releases, as to any entity or person . . . are . . . [a]ny liability to the State of California for any conduct other than the Covered Conduct."[57] Unlike the Nevada agreement, had the parties intended conduct similar to that alleged in Relators' Complaint be released in California, they would have included similar language. But they failed to do so.

Similarly, Relators' allegations were not part of that settlement agreement and were not released by Hawaii. That settlement agreement only applies to "covered conduct."[58] And, again, the "covered conduct" does not include Defendants' intentionally lying to FDB about its market prices—knowing that FDB would submit those prices to governmental entities.[59] All other conduct was specifically excluded from the terms of the settlement agreement. "[T]he State specifically does not release any person or entity from . . . any liability for any conduct other than the Covered Conduct."[60] Again, unlike the Nevada agreement, had the parties intended conduct similar to that alleged in Relators' Complaint be released in Hawaii, they would have included similar language.

Relators' allegations were likewise not part of the Illinois settlement and were not released by Illinois. That settlement agreement only applies to "covered conduct."[61] And, once

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[57] See Exhibit Q, p. 8 ¶15(f), attached to Defendants' Motion.

[58] See Exhibit R ¶ D, attached to Defendants' Motion.

[59] Relators' Complaint ¶ 25.

[60] See Exhibit R ¶ 7, attached to Defendants' Motion.

[61] See Exhibit S ¶ E, attached to Defendants' Motion.

again, the "covered conduct" does not include Defendants' intentionally lying to FDB about its market prices—knowing that FDB would submit those prices to governmental entities.[62] All other conduct was specifically excluded from the terms of the settlement agreement. "[T]he State specifically does not release any person or entity from . . . any liability for any conduct other than Covered Conduct."[63] Yet again, unlike the Nevada agreement, had the parties intended conduct similar to that alleged in Relators' Complaint be released in Illinois, they would have included similar language.

6. RELATORS CONCEDE THAT THE STARK CLAIMS SHOULD BE DISMISSED, BUT REQUEST LEAVE TO AMEND TO ALLEGE THAT THE SAME CONDUCT COMPLAINED OF VIOLATES STATE AND/OR FEDERAL ANTI KICKBACK STATUTES.

Baxter points out correctly that it cannot be liable under the terms of the Stark Act. (Defendants' Motion, p. 22). This argument is correct. However, it does not relieve Baxter of liability for concealing the discounts from CMS, and thereby underpaying rebates to the states. Relators below discuss their request for leave to amend their complaint to plead that the same facts establish violations of the Anti Kickback Statute, §42 U.S.C. 1320a-7b(b) as well as cognate state statues, e.g., California Welfare & Institutions Code §14107.2 and Illinois Statutes Ch. 305, §5/8A-3.

7. CONCLUSION

Relators have established that there are no bars to jurisdiction because the allegations in their complaint have not been publicly disclosed, and because in any event, they are the original

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[62] Relators' Complaint ¶ 25.

[63] See Exhibit S ¶ 7, attached to Defendants' Motion.

sources of any disclosures. Their claims have been set forth with sufficient specificity for 9b purposes.

Baxter's motion should be granted as to Counts II (the Stark Act claim), XII (Texas), XVI (Nevada), XX (Arkansas) and XXI (Utah). The motion should be denied in all other respects, and Relators should be given leave to amend their Complaint to add allegations that Baxter's conduct violate the federal and cognate state Anti Kickback Statutes.

Dated: September 15, 2009 LAW OFFICES OF MARK ALLEN KLEIMAN

By: /s/ Mark Allen Kleiman

MARK ALLEN KLEIMAN
California State Bar No. 115959
2907 Stanford Avenue
Venice, CA 90292
310-306-8094
310-306-8491 (fax)

DECLARATION OF MARK ALLEN KLEIMAN

I, Mark Allen Kleiman, hereby declare as follows:

I am an attorney duly licensed to practice before all courts in the State of California and am attorney of record for relators herein. If called upon to do so I could and would testify competently to the following based upon firsthand knowledge:

1. Before filing the complaint in this action I had two conversations about the allegations with Michael Theis while he was an Assistant United States in the United States Attorney's Office for the District of Colorado. Before taking this position Mr. Theis had been a Trial Attorney at the Department of Justice, where he had been primarily responsible for developing DOJ's liability theories for AWP cases.

2. The first conversation took place on or about January 30, 2005, and lasted approximately forty minutes. During this conversation I described the allegations in the proposed complaint, including the allegations that (a) Baxter's reporting was based on its prices to nonchargeback wholesalers which comprise only a small percentage of its market for biological products; (b) Baxter's deliberate refusal to report its WAC for Recombinate to First Databank, thus causing FDB to misreport Baxter's AWP for this product, and that this was done with Baxter's full knowledge consent decree with the Government, controlling Baxter's price reporting; and © use of Volume Committed contracting. Mr. Theis stated that he was quite interested in this information and that he would enjoy working on this case. Accordingly I sent Mr. Theis a draft of the complaint.

3. On March 1, 2005 Mr. Theis told me that he had read the complaint and had shared it with the Chief of the Civil Division. I told him we would get it filed shortly. He replied that he looked forward to it, and to working with us.

I declare under penalty of perjury of the laws of the State of Kentucky that the foregoing is true and correct. Executed this fourteenth day of September, 2009, in Louisville, Kentucky.

/s/ Mark Kleiman
Mark Kleiman

I, Linnette Sun, hereby declare as follows:

1. I am one of the Relators in United States ex rel Sun et al. v. Baxter. If called upon to do so, I could and would testify competently to the following based upon firsthand knowledge.

2. I started working in the pharmaceutical industry in 1992. I was initially employed by Merck & Company. I started as a business analyst and became a manager to work on health economics for the US Sales and Marketing Division. I worked at Merck for approximately five years.

3. I then went to work for Johnson & Johnson as the Associate Director and Director of Health Economics, primarily responsible for pricing. I held that position and those responsibilities for approximately two years.

4. I went to work for Amgen as an Associate Director of Health Economics with responsibility for pricing and reimbursement. I eventually became the Associate Director of Pricing in the corporate pricing department. I remained at Amgen from September, 1999 through June, 2002.

5. In June 2002 I was hired by Baxter International("Baxter") as the Director of Medical Outcomes Research and Economics. On the company's internal website I was referred to as the "Senior Director" of Medical Outcomes Research and Economics. I was hired to do global pricing(which included pricing in the United States as well as pricing for overseas markets), and the job description specifically included global pricing. I did not do medical research. My primary responsibility was pricing,

principally for a billion dollar product named Advate. I also did pricing for other Baxter products as well.

6. I was called by Nick Poulios, my immediate supervisor at Baxter, to attend a meeting even before I officially started at the company. This was a core pricing group meeting held at Baxter's Thousand Oaks, California facility. The core pricing group consisted of the highest level of pricing personnel at Baxter. The meeting was attended by approximately seven individuals, including John Park(Global Product Manager), Mr. Poulios (Senior Director of Medical Outcomes Research and Economics), Michael Baldridge (Director of Strategic Planning) and Mike Bradley (Director or Senior Director of Health Economics) The meeting included the Vice President of the global business unit which was responsible for Advate and a consultant from Simon Kucher, the most prestigious consulting firm in the world.
7. The objective of this core pricing meeting was to secretly discuss and decide on a discount price and a list price to be reported to First Data Bank ("FDB") and Redbook. The pricing consultant from Simon Kucher presented a pricing project that performed a choice modeling to see if the discounted price and margin would improve the market share for Baxter. John Park told me Simon Kucher was very expensive and Baxter paid one million dollars for this project. This meeting lasted an entire day.
8. Once my employment actually started, I was part of the task force for Advate pricing. As part of the task force, I was attended weekly core pricing meetings. This core group included Mike Bradley, John Park, Nick Poulios, Mike Baldridge and

someone at a director level from the European division of Baxter. This group had responsibility for pricing worldwide.

9. These core group pricing meetings would on occasion be attended by United States Marketing and Sales executives. Those executives would stress the importance of a high list price for payers to reimburse home health care companies and a low selling price to those companies. They kept telling us that as the front line managers they knew too well that Baxter can only sell if they provide economic incentives to these home health care companies.

10. As I was hired to do pricing for Baxter, I had full and complete access to all of Baxter's pricing documents. A document was prepared annually which set forth all of the competitive price information and market shares related to margins provided by other pharmaceutical companies to home health care companies for classes of blood products which Baxter BioScience competed most, along with pricing growth and market share growth over the years. This document was only distributed within a very limited group of people. Not everyone in the pricing core group received it, but I was one of the individuals who received it. John Park stressed how confidential this document was. I have a copy of this document. This document, along with the pricing report developed by Simon Kucher, was used by the core pricing group to decide how much of a discount Baxter should give home health care companies in order for Baxter to increase its market share. I did show the document to Nick Poulious, my immediate supervisor, and discussed with him the fact that the company that did the research listed margin and AWP on separate pages so that Baxter could

use this information to decide on the most favorable margin it could provide while still avoiding any legal problems in the event the government became aware of it.

11. Although Mike Bradley implemented all direct discounts for Baxter, the strategic decision on discounts and the margins was made by the core pricing group. We(the core pricing group) decided on the AWP and selling price. US Sales and Marketing tactically decided which home health care companies would receive the most discounts. I recall a core pricing group meeting at the backroom of the Westlake Hilton in early 2003. Mr. Poulios , Mr. Bradley, Mr. Baldridge and I were at the meeting. Mr. Park was absent as he was preparing for what was referred to as "price war gaming." I wanted to bring my consultant to the meeting but was told by John Park not to as the meeting was highly confidential. We discussed list prices (AWP) and contract prices for the US launching of Advate. Mr. Bradley highlighted several volume-committed contracts with major home health care companies to address concerns that the launch of the new product Advate would decrease Baxter's market share. He identified several major companies that had entered into these contracts with Baxter, that these contracts were good for three years and that they guaranteed certain discounts. Mr. Bradley told us home health care companies that did not buy and sell Baxter's products would be penalized. He further informed us of the actual discounts that Baxter was providing to these companies in these contracts and what the volume commitments were. Finally, Mr. Bradley stated that the volume committed contracts would generate majority of company revenues.
12. I challenged the notion that home health care companies could commit to a certain volume without adding additional patients. Assurances were given that these drugs

are safe and can be overdosed without serious side effects. It was further explained that although some patients become drug resistant, such patients may end up taking a large volume of Baxter products.

13. I stated at the meeting that these volume committed contracts are illegal, as I believed, based on my extensive experience with pricing, and my awareness of AWP litigation. Mr. Bradley said that Baxter would not get into legal trouble over these contracts because neither AWP nor margin was explicitly stated in these contracts, But in fact, he indicated that the margins were what the home health care companies were looking for, Baxter knew and we all knew that every single home health care company was aware of the AWP for reimbursement and the resulting margins that they would receive from the contract prices.

14. In mid 2003 I attended a decision-making meeting with the pricing core group and Larry Guiheen, the President of Baxter BioScience. The head of sales and marketing also attended via teleconference. The core pricing group members presented certain data and their recommendations. John Park, the global product director, and Peter Fan, his analysis manager, developed a spread sheet which contained the discount price, the AWP(which may be called "list price" in the spread sheet) and the margin (or spread, or delta in the spread sheet). This group, including the upper management people in attendance, voted at the meeting as to which selling price, list price and margin to offer to the home health care companies. I voted for the lowest margin as I did not feel the higher margins were legal. The overall vote was for a much higher margin. At the conclusion of the meeting, Mr. Guiheen directed the attendees at the

meeting to destroy all copies of this spread sheet, stating that he felt that Baxter could get in trouble over this spread sheet.

15. In my position I was one of the individuals involved in the decision as to what prices were to be reported to First Databank. The reporting of the list price would set the reimbursement price paid by government payers and private payers for the home health care companies. I performed research on this as part of my responsibility for pricing, I discovered some discrepancies in the prices listed for Baxter products between First Databank and Redbook. I therefore discovered that by using the word list price, twenty five percent would be added to this list price to calculate AWP. This meant that both government and private payers would end up paying twenty five percent more than the usual AWP. I brought this to the attention of Mr. Poulios and Mr. Park. John Park responded by telling me and the other members of the core pricing group that Redbook is the source that is primarily used for reimbursement. I then contacted First Databank. First Databank responded by email advising that First Databank was used by more than eighty percent of the payers in the United States, including government payers such as Medicare, Medicaid and Veterans Administration. I sent the email on to Mr. Poulious and Mr. Park. Mr. Poulious then scheduled a meeting on this issue with Mr. Guiheen. Mr. Guiheen directed me to not conduct any further investigation into this issue at the request of US Sales and Marketing management. He further stated that it may be a good thing for the home health care companies and those companies were taking advantage of this larger margin between the AWP and the selling price. This was also good for Baxter as the home health companies would be more likely to use Baxter products. In other words,

Baxter could sell more as a result of this erroneous reporting. The larger the margin was between AWP and selling price, the greater the economic incentive was for home health care companies to buy Baxter products.

16. While I was at Baxter, I participated in all pricing meetings for all Baxer BioScience projects. One project we had included an offsite meeting at the Westlake Hilton Hotel for discounting and margin simulations, which were referred to as "war games." There were participants from all over the world, all of whom were at a management level. The meeting was chaired by John Park. There was a discussion at the meeting about how to inflate the reimbursement prices for Baxter products while lowering selling prices, which would result in higher sales to those providers with larger margins. US Sales and Marketing management concluded that only larger margins would generate higher sales and greater revenue.

17. After I expressed my concern and challenged this margin scheme developed and practiced by Baxter to increase its revenues by millions of dollars, Baxter terminated my employment.

18. Based on my position at Baxter, the information I had access to, the meetings I participated in, the decisions that I was involved in, the communications I had with First Databank and others outside of Baxter, and the research that I conducted, I had direct knowledge of the prices Baxter reported, and therefore had direct knowledge that Baxter reported and false and inflated AWPs, that generated more sales and revenue for Baxter at the expense of both government and private payer money.

I declare under penalty of perjury under the laws of the State of Pennsylvania of America that the foregoing is true and correct. Executed this 14th day of September, 2009, at Wayne, Pennsylvania

Linnette Sun

DECLARATION OF GREG HAMILTON

I, Greg Hamilton, hereby declare as follows:

1. I am one of the Relators in United States ex rel Sun et al. v. Baxter. If called upon to do so, I could and would testify competently to the following based upon firsthand knowledge.

2. I have worked for pharmaceutical manufacturers and pharmacy benefit managers for over twenty years. During this time I have had extensive contact with Baxter's senior staff as a customer, a colleague and as a competitor. This contact has included numerous meetings Guiheen (the President of Baxter BioScience who is referred to in ¶45 of the Complaint) as well as his superior, Peter O'Malley. Those meetings specifically concerned the pricing of several of the Baxter products discussed in this Complaint.

3. From 2001 – 2004 I was the Senior Director of Strategic Sales and Planning at Specialty Distribution Services for Express Scripts, the Pharmacy Benefit Manager. From 2004 – 2006 I was the Vice-President of the Curascript Bleeding Disorder Program. (CuraScript is an operating division of Express Scripts.)

4. While serving in these positions I frequently met with Baxter's senior management to discuss the market for hemophilia products. Because the market for hemophilia products is extremely lucrative, national hemophilia meetings were typically attended by the leadership from concerned pharmaceutical companies and PBMs. At these conferences I would hold scheduled meetings with Larry Guiheen, who was then Baxter's Vice-President for North America, as well has his boss, Peter O'Malley. I also made at least three trips to Baxter's Deerfield, Illinois, offices to meet with Baxter managers to discuss pricing. At least one of those meetings took place at the request of Peter O'Malley, who was either Baxter's President of North American operations, or vice President of Sales. O'Malley asked me to meet with Baxter's contracting

staff and describe how to price products for Government customers, and how pricing for the 340B program operates.

5. I had at least three such meetings with Baxter to discuss pricing in barely a year – August 8, 2002, February 3, 2003, and September 26, 2003.

6. During one such meeting I had a long discussion with Larry Guiheen about Baxter's pricing of Advate (Baxter's version of Recombinant Factor VIII.) Within a few months of this meeting Baxter changed its price for Advate to within a penny of what I had recommended.

7. In addition to being a major customer of Baxter's through my work with Express Scripts and Curascript, I also interacted with Baxter's pricing managers as a competitor of Baxter's when I worked for Bayer. While working for Bayer, I served with Baxter executive Peter O'Malley on the Plasma Protein and Therapeutics Association's Reimbursement Committee, and Drug Recall Committee, and had numerous discussions with him about pricing strategies.

8. In addition to my direct discussions with Baxter managers, I learned of Baxter's pricing and some of the specific acts alleged in ¶¶ 36-40 of our complaint while trying to help Kay Morgan, Manager of Editorial Services for First Data Bank. In May or early June of 2001 Kay Morgan called and asked my opinion about why Baxter was refusing to provide its WAC for Recombinate. She told me that Baxter sent a letter saying that their list price was $1.31 and they wanted their AWP reported as $1.31. She told me that when she asked Baxter for the WAC, Baxter merely repeated that the list price for Recombinate was $1.31 and that they wanted the AWP reported as $1.31. Morgan told me that FDB was so mad that they threatened not to publish any information at all.

9. Morgan told me that she, her boss, and the FDB legal department wrote a letter to Baxter threatening that FDB would refuse to publish the AWP information.

10. Morgan asked me what I thought Baxter was trying to accomplish by this. I told her that I thought Baxter's goal was to establish an AWP was attractive to the distributors, but to still be able to deny to the hemophilia community that it was Baxter's fault for the high AWP, and to blame FDB.

11. Throughout my years in the industry I was able to achieve a high level of understanding of Baxter's pricing structure from direct discussions with Baxter's senior management, as well as through the information given me by FDB.

12. The Market Research Bureau's PLASMA FRACTIONS MARKET IN THE US report is an annual publication for the Plasma industry. This industry is a classic oligopoly consisting of less than 7 manufacturers.

13. The Market Research Bureau was founded and is operated by Patrick Robert, a former Bayer employee and colleague. He left Bayer and created MRB in the mid 90's to provide the Plasma industry with a much needed data source. The standard source for the drug industry is IMS Health, however they do not audit/cover plasma products.

14. On September 13, 2009 I called The Market Research Bureau and spoke with Cindy Lynn, Patrick Robert's secretary. She told me that a single issue of this publication costs $16,000, and that there are fewer than 20 subscribers, including manufacturers, a few specialty pharmacies, and a few 340d entities. She also told me that they do not sell or give any of their reports to university libraries or public libraries.

I declare under penalty of perjury under the laws of the state of Illinois that the foregoing is true and correct. Executed this 15th day of September, 2009, at Algonquin, Illinois.

/s/ Greg Hamilon

Greg Hamilton

CERTIFICATE OF SERVICE

I hereby certify that I, Mark Kleiman, an attorney, caused a true and correct copy of the foregoing, **MEMORANDUM IN OPPOSITION TO BAXTER INTERNATIONAL INC.'S MOTION TO DISMISS RELATORS' COMPLAINT**, to be delivered to all counsel of record by electronic service on September 15, 2009, for the posting and notification to all parties.

By: /s/ Mark Allen Kleiman

MARK ALLEN KLEIMAN
California State Bar No. 115959
2907 Stanford Avenue
Venice, CA 90292
310-306-8094
310-306-8491 (fax)